

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

BETTY FUNDERBURKE,)	
)	
Plaintiff,)	Master File No. 2:12-MD-02327
)	MDL No. 2327
v.)	
)	
ETHICON, INC., ETHICON WOMEN'S)	JOSEPH R. GOODWIN
HEALTH AND UROLOGY, a Division of)	U.S. DISTRICT JUDGE
Ethicon, Inc., GYNECARE, JOHNSON &)	
JOHNSON,)	
)	
Defendant.)	

PLAINTIFF'S RESPONSE IN OPPOSITION TO DEFENDANTS'
MOTION FOR SUMMARY JUDGMENT

Plaintiff, BETTY FUNDERBURKE, by and through her counsel, as her Response in Opposition to Defendants' MOTION FOR SUMMARY JUDGMENT, states as follows:

INTRODUCTION

Defendants' Motion for Summary Judgment seeks judgment as a matter of law on all of the claims in Plaintiff's Complaint. Plaintiff opposes Defendants' motion with respect to the following counts: Negligence (Count I) and Gross Negligence (Count XIV).

Plaintiff agrees with Defendants that North Carolina law applies to this case.

STATEMENT OF ADDITIONAL UNDISPUTED FACTS

Plaintiff submits these additional, undisputed facts to Defendants' Statement of Undisputed Facts:

1. Plaintiff's implanting physician, Dr. Adams-Denny, testified that she understood from the Instructions for Use ("IFU") warning that the adverse reaction of extrusion and erosion

was a minor complication. *See* Ex. A, Dr. Natasha Adams-Denny 11/10/15 Dep. Tr. at 32:23 – 34:3.

2. Dr. Adams-Denny testified that Ethicon never told her that mesh could cause a rigid scar plate; a dense, fibrous scar plate; or a thick scar plate. *Id.* at 34:15 – 35:14.

3. Dr. Adams-Denny testified that Ethicon never told her and she was unaware prior to Plaintiff's surgery in 2008 that infection or erosion necessitates the removal of the mesh, which is difficult to do. *Id.* at 35:16 – 36:3.

4. Dr. Adams-Denny testified that Ethicon never told her and she was unaware prior to Plaintiff's 2008 surgery that the mesh could lose up to 18.15 percent of its weight due to mesh particle release. *Id.* at 36:13 – 22.

5. Dr. Adams-Denny testified that Ethicon never told her and she was unaware prior to Plaintiff's surgery in 2008 that as of May 6, 2006 Ethicon got a high number of complaints on latching and roping, mesh particles falling off, and material stretching to the point of getting a string. *Id.* at 40:10 – 41.5.

6. Dr. Adams-Denny testified that she read the IFUs for TVT-O and Prolift before implanting them in Plaintiff. *Id.* at 112:13-24; 27:6-13.

STANDARD OF REVIEW

The district court should only grant a motion for summary judgment when there is no genuine dispute as to an issue of material fact, and the moving party is entitled to judgment as a matter of law. *Nguyen v. CNA Corp.*, 44 F.3d 234, 236 (4th Cir. 1995) (quoting Fed.R.Civ.P. 56(c)). The district court, in considering a motion for summary judgment, must not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Indeed, the court must draw all permissible inferences from the underlying facts in the

light most favorable to the non-moving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

ARGUMENT

I. Plaintiff's Claims are not Barred by the Statute of Limitations.

North Carolina has a three-year statute of limitations for claims involving personal injury; however a cause of action for personal injury “shall not accrue until the bodily harm to the claimant . . . becomes apparent or ought reasonably to have become apparent to the claimant, whichever event occurs first.” N.C. Gen Stat. §1-52(16). The parties agree that Plaintiff was implanted with a Prolift and TVT-O device on December 31, 2008, underwent revision surgery on March 31, 2009, and filed her complaint on March 22, 2012. The parties further agree that Plaintiff's treating physician first noted areas of exposed mesh and first recommended vaginal mesh revision surgery on March 27, 2009.

Although Defendants acknowledge that Plaintiff's treating physician, Dr. Natasha Adams-Denny, first indicated to Plaintiff that she needed revision surgery on March 27, 2009, Defendants insist that the statute began to run no later than January 26, 2009, a full two months before Plaintiff's first post-operative appointment with her physician. Defendants have no basis in fact or under the laws of North Carolina law to assert January 26, 2009 as the accrual date.

Factually, Defendants' assertion of January 26, 2009 as the accrual date is unfounded because Plaintiff's description of her discomfort post-surgery does not rise to the level of awareness of bodily harm, the operative language under the North Carolina statute. Defendants point only to Plaintiff's testimony in deposition that, at some point after the December 31, 2008 implantation surgery, she experienced a sticking sensation that she associated with the mesh. *See* Ex. B, Betty Funderburke 10/23/15 Dep. Tr. at 132:9-22. A question of fact remains as to whether

“sticking” constitutes apparent bodily harm or even bodily harm that ought reasonably to have been apparent, such that it satisfies the language of N.C. Gen Stat. §1-52(16); or whether, at that time, Plaintiff subjectively believed—and a reasonable person would have believed—that it was merely a post-surgical complaint that her implanting physician could address.

In fact, Plaintiff’s state of awareness *before* her March 27, 2009 consultation with Dr. Adams-Denny is an open question of fact, particularly given her testimony that she did not know what was causing her problems:

Q: At any time after Dr. Denny put in the mesh to now, has any doctor told you that it was the mesh causing your problems?

A: No, ain’t no doctor told me that. But when it come down and I felt all this sticking and everything, I’d go back to Dr. Denny and she’d say, Well – she examined me and she’d have to go back up in me, so I knew it was the mesh.

Q: Did you think you were doing something wrong?

A: Well, I didn’t know. I mean, yeah, I figured why was it happening to me and I was the only one that was – I mean, you know. And I didn’t know. Nobody never told me what to expect, what to look for. And so I really didn’t know what to expect and what to look for.

Q: And you didn’t know what was causing your problems?

A: No.

Id. at 149:17 – 150:10.

Neither of the cases from the Southern District of West Virginia cited by Defendants support Defendants’ assertion that a plaintiff’s perception of discomfort post-surgery is tantamount to awareness of bodily harm or reason to be aware of bodily harm, particularly before a treating physician has alerted the plaintiff that the discomfort is the result of injury. In *Robinson v. Boston Scientific Corp.*, No. 2:12-cv-03700, 2015 WL 1466746 (S.D. W. Va. March 30, 2015), the court concluded that the statute began to run when the plaintiff saw her implanting physician

complaining of dyspareunia, *and the physician told her that he thought the mesh was causing her symptoms. Id.* at *5. Similarly, in *Timothy v. Boston Scientific Corp.*, No. 2:12-cv-05950, 2015 WL 1405498 (S.D. W. Va. March 26, 2015), the court determined that the accrual date was the day the plaintiff saw her physician, *and he informed her that he believed that the mesh was causing her bleeding* and he would repair it in his office. *Id.* at *3.

The only North Carolina state court decision cited by Defendants is totally inapposite because it concerns physical damage to real property. *McCarver v. Blythe*, 147 N. C. App. 496 (2001). The accrual date was fixed as of the date that the plaintiff in *McGarver* admitted to visiting the property and noticing that the porches and roof were rotting, that boards needed to be replaced, and the roof needed to be sheathed. *Id.* at 499-500. This is apparent harm that a lay person is capable of detecting; whereas harm to the body can be latent, often deceptive, and frequently requires a physician's identification. When all permissible inferences are drawn in favor of the Plaintiff, it cannot be said that Plaintiff was aware or should have been aware that she had suffered bodily harm on the basis of her post-operative perception of a sticking sensation that prompted her to consult with her physician.

Next, drawing all inferences in favor of Plaintiff, there is a question of material fact about when Plaintiff began to perceive the sticking sensation. All of Plaintiff's statements about when she became aware of the sticking sensation are equivocal and cannot be tethered to the date of January 26, 2009. Plaintiff said that it "seemed" like two to three weeks after her surgery, and she immediately admitted that, in fact, she did not know when it began:

Q: So to the best of your ability, can you tell me when you first started having complications after your surgery?

A: Two or three weeks – well, it seemed like, now. I don't know. It seemed like two to three weeks after.

See Ex. B, Betty Funderburke 10/23/15 Dep. Tr. at 75:16-18.

Finally, it would be improper to confuse Plaintiff's current understanding of what the sticking sensation meant with her understanding of what it meant in January of 2009. It is immaterial that Plaintiff may now, looking back, regard the sticking sensation she experienced in January of 2009 as a "complication" or that she may *now* understand it to be a sign of the harm that she subsequently discovered with the help of her physician. The question of fact is whether she was aware or had reason to be aware before she saw her physician on March 27, 2009 that she had suffered actual bodily harm.

Defendants emphasize that Plaintiff's testimony reveals that she knew that the source of her sticking sensation was the mesh, but plaintiff's awareness of the cause is immaterial under North Carolina law which, as Defendants note, requires only knowledge of injury, not knowledge of its cause. The pertinent point is that Plaintiff did not have reason to be aware of *injury* until she consulted with her physician and injury was identified for her. There is no basis in the law cited by Defendants to correlate Plaintiffs' awareness of an uncomfortable sticking sensation with the requisite conclusion that bodily harm was or ought to have been apparent.

Plaintiff filed her complaint on March 22, 2012 within three years of the March 27, 2009 date when her implanting physician informed her of mesh erosion and the need for revision surgery. Therefore, none of Plaintiffs' claims are time barred.

II. Defendants' Motion for Summary Judgment on Plaintiff's Failure-to-Warn Claim Must Be Denied Because Genuine Issues of Material Fact Exist with Respect to Plaintiff's Implanting Physician's Awareness of the Risks Associated with Prolift and TVT-O and Whether an Adequate Warning Would Have Led to a Different Result.

Plaintiff agrees with Defendants that to prevail on a claim for failure to warn under North Carolina law, a claimant must prove: 1) that the manufacturer or seller acted unreasonably in

failing to provide an adequate warning; 2) that the failure to provide adequate warning was the proximate cause of the harm to the claimant; and 3) either of the following:

- (1) At the time the product left the control of the manufacturer or seller, the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant.
- (2) After the product left the control of the manufacturer or seller, the manufacturer or seller became aware of or in the ordinary exercise of care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

N.C. Gen. Stat. § 99B-5(a).

Defendants' motion for summary judgment on Plaintiff's claim for failure to warn disputes Plaintiff's ability to prove proximate cause. Defendants insist that Plaintiff cannot establish that Dr. Adams-Denny relied on Ethicon's product warnings and that there is no genuine issue of material fact that Dr. Adams-Denny was aware of the risks associated with the Prolift and TVT-O when she performed Plaintiff's surgery. Genuine issues of material fact exist with respect to both issues raised by Defendants.

A. Dr. Adams-Denny's Testimony Presents a Question of Fact as to Whether an Adequate Warning Would Have Led to a Different Result.

Defendants ask this Court to find that Plaintiff cannot show that an adequate warning would have led to a different result because Dr. Adams-Denny stated that she didn't rely on the Prolift and TVT-O IFUs in deciding to perform the surgery on Plaintiff. Dr. Natasha Adams-Denny 11/10/15 Dep. Tr. at 113:25 – 115:6. Defendants cite *Frankum v. Boston Scientific Corp.*, No. 1:15-CV-00091-MOC, 2015 WL 3514327 (W.D.N.C. June 4, 2015) for the proposition that reliance is a necessary element of causation, and extrapolate that summary judgment is warranted because Dr. Adams-Denny said that she did not "rely" on the IFUs. Such an extrapolation elevates

Dr. Adams-Denny's conclusory manner of expression over the substance of her testimony and the substance of the North Carolina cases cited by Defendants in ostensible support for their position. In all of the cases decided under North Carolina law cited by Defendants, the court reached the conclusion that the Plaintiff could not show that the physician relied on the IFUs because the physicians admitted *that they had not read the IFUs*. Dr. Adams-Denny testified that she "definitely read" the TVT-O and Prolift IFUs before implanting them in Plaintiff. *See* Ex. A, Dr. Natasha Adams-Denny 11/10/15 Dep. Tr. at 112:13-24. 27:6-13.

Dr. Adams-Denny's unambiguous factual statement that she read both IFUs before Plaintiff's surgery distinguishes this case from all of the cases decided under North Carolina law cited by Defendants. In *Frankum v. Boston Scientific Corp.*, No. 1:15-CV-00091-MOC, 2015 WL 3514327 (W.D.N.C. June 4, 2015), cited by the Defendants for the proposition that reliance is a necessary element of causation, the implanting surgeon admitted that he did not read the IFU for the product at issue, prompting the MDL Court to conclude that the facts demonstrate that the implanting surgeon "failed to *rely*" on the IFU. *Id.* at *2 (emphasis in original). In *Sparks v. Oxy-Health, LLC.*, defendant's motion for summary judgment on a failure to warn claims was granted because of plaintiffs' "collective failure to read the Reference Manual." *Sparks v. Oxy-Health, LLC*, No. 5:13-CV-649-FL, 2015 WL 5773591 at *24 (E.D.N.C. Sept. 15, 2015). In *Felan v. Boston Scientific Corp.*, the court's conclusion that the record demonstrated no reliance rested, at least in part, on the absence of any evidence that the prescribing physician had read the DFU. *Felan v. Boston Scientific Corp.*, 2015 WL 2137180, at *4 (S.D. W. Va. May 7, 2015).

These cases, decided under North Carolina law, stand for the proposition that the failure to read the IFU eliminates all genuine issue of material fact with regard to the physician's reliance, not a physician's denial of "reliance"—however she may understand that word—against the

backdrop of copious testimony that a reasonable juror might determine indicates reliance. Dr. Adams-Denny testified that she “definitely read” the TVT-O and Prolift IFUs before implanting them in Plaintiff. *See* Ex. A, Dr. Natasha Adams-Denny 11/10/15 Dep. Tr. at 112:13-24; 27:6-13. She testified that she got information about the TVT-O and Prolift devices from a Gynecare representative and from an Ethicon training course that she attended prior to Plaintiff’s surgery, that she relies on medical device manufacturers to provide truthful information about their devices, and that she believes that Ethicon did not provide her with sufficient information to fully understand the risks associated with the Prolift prior to implanting it in the Plaintiff. *Id.* at 14:13 - 18:3.

Specifically, Dr. Adams-Denny testified that Ethicon did not tell her that erosion necessitates removal of the mesh, and that had she known that erosion could necessitate removal of the mesh, she would “probably not” implanted Plaintiff with the mesh. *Id.* at 35:23 - 36:11. Dr. Adams-Denny testified that Ethicon did not give her the following information that would have negatively influenced her decision to use the mesh: that the mesh could cause a rigid scar plate, a dense fibrous scar plate or a thick scar plate; that the mesh could lose up to 18.15 percent of its weight due to mesh particle release; that a doctor had communicated to Ethicon that he thought the mesh erosions were underestimated in reports; that a doctor had communicated to Ethicon that he believed that the erosions with the mesh were due to the sharp edges of the mesh; that there was a twenty to thirty percent incidence of leg pain with the mesh, that Ethicon wanted to laser cut the mesh to eliminate particle release; that Ethicon had received a high number of complaints on lenthing and roping, mesh particles falling off and material stretching to the point of getting a string. *Id.* at 34:15 – 42:2.

With respect to whether an adequate warning would have led to a different decision for Dr. Adams-Denny's use of the Prolift, she testified that she was familiar with the Prolift IFU prior to Plaintiff's surgery. *Id.* at 44:17 - 45:5. She testified that she understood from the training she received from Ethicon that the Prolift, as it is described in the IFU, affords excellent strength, durability, and surgical adaptability with sufficient porosity for necessary tissue in-growth. *Id.* at 45:20 - 46:7. Whatever Dr. Adams-Denny may have intended when she opined that she did not "rely" on the IFU, a genuine issue of material fact remains as to whether an adequate warning would have led to a different result when her deposition testimony is taken as a whole and construed in the light most favorable to the Plaintiff.

B. Dr. Adams-Denny's Testimony Presents a Question of Fact as to Whether She was Aware of the Risks Associated with the Prolift and TVT-O at the Time She Performed Plaintiff's Surgery.

Contrary to Defendants' contention that Dr. Adams-Denny was aware of the risks associated the Prolift and TVT-O devices when she performed the implantation surgery on Plaintiff, there is abundant testimony from Dr. Adams-Denny that she was unaware of specific risks associated with these devices and unaware of the seriousness of those risks. Notably, Dr. Adams-Denny was not aware of the unique risk posed by certain complications necessitating the removal the mesh device. *See* Ex. A, Dr. Natasha Adams-Denny 11/10/15 Dep. Tr. at 183:3-19. She was not aware of the seriousness of the adverse reaction of extrusion and erosion. *Id.* at 32:23 - 34:3. She was not aware that mesh could cause rigid scar plates; dense, fibrous scar plates; and thick scar plates. *Id.* at 34:15 - 35:14. Dr. Adams-Denny testified that she was unaware that mesh could lose up to 18.15 percent of its weight due to mesh particle release. *Id.* at 36:13 - 22. She was unaware that as of May 6, 2006 Ethicon got a high number of complaints on lenticing and roping, mesh particles falling off, and material stretching to the point of getting a string. *Id.* at 40:10 -

41:5. This testimony presents a disputable issue of material fact with regard to Dr. Adams-Denny's awareness of the risks posed by Prolift and TVT-O at the time of Plaintiff's surgery. Therefore summary judgment must be denied.

III. Defendants' Motion for Summary Judgment with Respect to Plaintiff's Claim for Gross Negligence Must be Denied because there is a Genuine Issue of Material Fact as to Whether Defendants' Conduct Constitutes Gross Misconduct.

Defendants invoke *Yancy v. Lea* as ostensible support for their motion for summary judgment on Plaintiff's claims for gross negligence. In *Yancy*, the North Carolina Supreme Court characterized gross negligence as "deliberate misconduct affecting the safety of others." *Yancy v. Lea*, 550 S.E.2d 155, 158 (N.C. 2001). *Deliberate* misconduct is precisely how Plaintiff characterizes Defendants' withholding of information about its products' risks. The North Carolina Supreme Court's admonition that the distinction between negligence and gross negligence is not in the degree or magnitude of inadvertence or carelessness does not invalidate Plaintiff's claim. Plaintiff has alleged that Defendants actively and *intentionally* misled the physicians into believing that the Defendants' Pelvic mesh products were safe and effective. Complaint, ¶26. Whether the Defendants' representations misled the public and implanting surgeons is precisely the issue of material fact in dispute in this case. Accordingly, a motion for summary judgment is wholly inappropriate at this stage of the litigation. Defendants' motion with regard to this count must be denied.

WHEREFORE, Plaintiff respectfully requests that this Court deny Defendants' Motion for Summary Judgment with regard to Count I (Negligence) and Count XIV (Gross Negligence) of Plaintiff's Complaint.

DATED: April 20, 2016

/s/ Frank V. Cesarone
Frank V. Cesarone (#06210847)

fvc@meyers-flowers.com
Meyers & Flowers, LLC
3 North Second Street, Suite 300
St. Charles, Illinois 60174
Phone: (630) 232-6333

CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service herein.

/s/ Frank V. Cesarone
Frank V. Cesarone (#06210847)
fvc@meyers-flowers.com
Meyers & Flowers, LLC
3 North Second Street, Suite 300
St. Charles, Illinois 60174
Phone: (630) 232-6333

Counsel for Plaintiff(s)